Exhibit L

Brad Hammock
Email: bthammoc@dollartree.com

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Highly Confidential Business Information

Via Email

Chad J. Whitwell
Compliance Officer
Office Human and Animal Food Operations Division 3 West (TX, OK, AR)
Office of Regulatory Affairs
Chad.Whitwell@fda.hhs.gov

Dear Officer Whitwell:

Thank you for the opportunity to respond to the Agency's concerns about the fumigation process and the impact of the potential rodent-related issues and reconditioning practices implemented at the Family Dollar Distribution Center, located in West Memphis, AR (the "DC"), to prevent potentially adulterated product to enter commerce. Family Dollar conducted an evaluation and assessment of the activities and practices implemented at the DC. This Health Hazard Evaluation was conducted in consultation with EAS Consulting Group, LLC (EAS), an independent quality assurance and regulatory consulting firm. Our evaluation, as more fully set forth below, confirms the following:

- A successful fumigation process was performed on January 15-16, 2022, based on the review of the documentation provided by the company in charge of the fumigation.
- Control of safety hazards on human food, over the counter (OTC) drug, OTC device, and animal food by the removal of rodent filth through reconditioning practices. We present the information collected to date from the implementation of these reconditioning practices at this DC and a risk-based matrix assessment.
- Health hazards associated with the fumigation process, based on a detailed evaluation of documents provided by the fumigant distributing company, the approval of this fumigant, and several scientific publications. This evaluation is focused on potential human food, OTC drug, OTC device, and animal food safety hazards generated by the fumigation process.

We would like to emphasize that our previous evaluation has provided evidence that no product released to commerce by Family Dollar has been found contaminated, and that Family Dollar has protocols in place to detect contamination at the DC and its retail stores. In addition, Family Dollar has implemented detailed product assessment practices to identify and segregate potentially adulterated product in this DC.

500 Volvo Parkway, Chesapeake, VA 23320
Main (757) 321-5000 Fax (757) 321-5949

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Successful Fumigation Process

The fumigation process in the DC was successful in reaching the target minimum level of 36 oz·h/1000ft³ (gas level), as set forth by the manufacturer to be lethal to control the rodent infestation in the facility. Please refer to attached document 2022-1-14 Family Dollar Fumiguide report.

Control of Food Safety Hazards by Reconditioning Practices and Health Hazard Evaluation of Rodent Filth

In preparing this Health Hazard Evaluation, we evaluated the following documents related to DC's pest control and reconditioning procedures:

- DC 202 Assessment and Reconditioning Standard Operating Procedure. Version 1, January 22, 2022
- DC Pest Control and Product Reconditioning Standard Operating Procedure. Version 1, January 22, 2022

Family Dollar, in consultation with EAS, has also organized a risk-based matrix assessment to categorize human food, OTC drug, OTC device, and animal food. This matrix assessment is based on the number of packaging materials and the degree of imperviousness of the packaging material to prevent potential contamination of product by rodent filth or otherwise. We also summarize the findings after reviewing the documents created throughout our reconditioning SOP to ensure compliance with these practices. This procedure also highlights any need for improvement of these practices to further prevent any potentially contaminated product from being released from the DC.

Risk-Based Matrix Assessment

As stated above, Family Dollar developed a risk-based matrix to categorize products based on the number of packaging materials they contain and the degree of imperviousness of packaging material. This package material matrix is applicable to all product categories (*i.e.*, human food, OTC drug, OTC device, and animal food) as it is based on the ability of the package materials to shield and protect the contents from potential contamination. The following matrix was developed:

500 Volvo Parkway, Chesapeake, VA 23320
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		Degree of Imperviousness of Packaging Material[1]		
		Low	Medium	High
Number of Packaging Material (Barriers)[2]	1	A1	B2	B4
	2	A2	B3	C1
	3	B1	C2	C3

In this matrix, the product packaging materials and package configuration categories are defined based on their imperviousness or ability to resist the absorption or migration of possible rodent contamination and/or fumigant material directly to the product contained within the primary package. A low degree of imperviousness will allow for a higher risk of potential product contamination, and vice-versa.

- Categories A1 - A2. Products (*i.e.*, human food, OTC drug, OTC device, and animal food) in these categories have packaging material with a low degree of imperviousness, such as the products that have paper, perforated plastic film or cardboard as the primary packaging material. These categories represent a higher potential risk of contamination, but the DC's protocols, as well as similar processes implemented across Family Dollar at its retail Stores, are designed to detect and discard potentially contaminated product before they are released for sale to consumers.
- Categories B1 - B4. Products (*i.e.*, human food, OTC drug, OTC device, and animal food) in these categories are more protected from possible environmental contaminants, and packaging materials have a medium degree of imperviousness. These categories include products that have plastic over-wrapping impervious to water, heat sealed poly-film bags, and single layer waxed paper/cellophane pouching/wrapping as their primary packaging material.
- Categories C1 - C3. Products (*i.e.*, human food, OTC drug, OTC device, and animal food) in these categories have two (primary and secondary) or more packaging materials, and the materials have a medium to high degree of imperviousness. Package materials of this type include HDPE bottle, vacuum sealed cans/jars, multi-layer polyfoil blister cards, etc. These categories represent the product with the least amount of risk for potential contamination.

All products (*i.e.*, human food, OTC drug, OTC device, and animal food) in Categories A1 and A2 that show any visual, external contamination of primary packaging will be tagged and

[1] Imperviousness relates to the potential passage of chemical and biological hazards through the packaging material and then contacting product.
[2] Package number 1 represents primary packaging --the one contacting with product (*i.e.*, human food, OTC drug, OTC device, and animal food).

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considered contaminated. Likewise, products (*i.e.*, human food, OTC drug, OTC device, and animal food) in Categories B1 through B4 and C1 through C3 that lack primary package integrity (damaged, missing, altered, etc.) will also be considered contaminated. These products will not be reconditioned and will be disposed of according to our current practices. All products in this category with visual contamination only of the secondary packages, but with intact primary packages, will be reconditioned following current practices.

Based on the review of documents collected through the implementation of DC 202 Assessment and Reconditioning Standard Operating Procedure, the products (*i.e.*, human food, OTC drug, OTC device, and animal food) in Categories A1 and A2 are properly managed to prevent the release into market of products that are potentially contaminated.

Products (*i.e.*, human food, OTC drug, OTC device, and animal food) within Categories B1 - B4, and C1 - C3, are evaluated, segregated if necessary, and reconditioned according to DC 202 Assessment and Reconditioning Standard Operating Procedure. All reconditioned products have packaging material that act as barriers to prevent the migration of any outside hazard into the products. A review of the documents collected through the implementation of this process shows that potentially contaminated products are tagged and reconditioned to remove any contaminants present before they are released.

It is important to emphasize that the information provided in Family Dollar's letter submitted to the Agency on January 19, 2022, regarding the protocol to prevent potentially contaminated or otherwise adulterated product from being offered for sale at Family Dollar's retail stores, is still in place.

Our assessment indicates that all products (*i.e.*, human food, OTC drug, OTC device, and animal food) evaluated to date for potential contamination by rodent filth has been consistent with the barriers provided by the package materials and the configuration matrix results outlined above. Thus, the reconditioning inspection/assessment process has been successful to identify product requiring reconditioning. Based on the product inspections to date, we have disposed of approximately 150 tons of product with potential damage. There is additional product that has been segregated and is awaiting disposal.

Health Hazard Evaluation of the Fumigation Process

Our hazard evaluation was performed by reviewing several documents provided by fumigant distributor Douglas Products, the approval of this fumigant with the Environmental Protection Agency (EPA), and several scientific publications to determine if this fumigant, or any of its residues, may pose a safety hazard to the FDA-regulated products at the DC. Because this is a federally restricted use pesticide, the application of this fumigant is only performed by certified companies that follow protocols to prevent any human exposure. Thus, we are not addressing any human health issues that may arise from the inappropriate use of this fumigant.

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The product used during the fumigation process was sulfuryl fluoride (ProFume® Gas Fumigant, Douglas Products), which is a safe fumigant that was first marketed in 1961 by Dow Chemical (Vikane®). Some of the properties of this compound makes it one of the preferred fumigants for use in the grain and food industries. Its wide range of food tolerances allows this product to be used on different commodities, including mills, food processing facilities, warehouses, storage containers, and transportation vehicles. This inorganic gas is also a preferred method to control rodent pests in food facilities.

This inorganic gas does not leave residues on inert surfaces, such as stainless steel, glass and ceramic, and rapidly aerates from materials and commodities. In addition, this gas has the following properties:

- Nonflammable, odorless, colorless and rapidly vaporizes;
- Noncorrosive and distributes quickly without affecting sensitive equipment or electronic devices; and
- Non-reactive with materials to form other by-products or result in unpleasant odors or flavors.

Application to OTCs

The Douglas Products, "Applicator Manual for ProFume® gas fumigant" (attached, page 27) states that when using the sulfuryl fluoride gas fumigant agent prior to fumigation, measures should be taken to: "Remove from the structure to be fumigated all persons, non-target animals, and desirable growing plants. All drugs (including tobacco products) and medicinals (including those items in refrigerators and freezers) need to be removed prior to fumigation."

Despite this statement, we believe the use of this fumigant does not represent a risk to intact, packaged OTC drug products which were present in the facility at the time of fumigation. The purpose of this fumigant according to the Applicator Manual (page 1) is to be used on "Sites to be fumigated: Non-residential structures, food handling establishments (e.g., pet food facilities, bakeries, food production facilities, mills, warehouses, etc.), stationary transportation vehicles (railcars, shipping containers, trucks, etc., excluding aircraft and passenger railcars), temporary and permanent fumigation chambers, and storage structures." Thus, the suitability of the fumigant for food processing and storage facilities indicates that the potential incidental (one time) exposure of OTC drug products to this gaseous fumigant does not pose a meaningful risk given the type of drug packaging materials and configurations.

Any OTC drug product package that is intact, unopened, and free from damage or defect, by its very design and nature, is supposed to be impervious to, and able to protect the drug product inside from, general environmental contaminants. Further, given that all OTC drug products housed

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within the facility represent commercially released and distributed packaged products that are required under the Current Good Manufacturing Practices (CGMP) regulations to have been verified to meet the component acceptance and release requirements of 21 CFR § 211.84(d)(2) and (d)(3) and 21 CFR § 211.122(b), we believe that such drug product packaging components would adequately prevent any direct OTC drug product from getting exposure to the fumigant. This effectively eliminates the possibility of direct product exposure, fumigant contamination or chemical reaction that would jeopardize the safety, identity, strength, quality or purity of the packaged OTC drug products.

Registration, Use, and Residue Tolerances

Sulfuryl fluoride is registered as a "antimicrobial pesticide" with the EPA through The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), which is the statute governing the registration, distribution, sale, and use of pesticides in the USA. There are tolerance levels that have been established for residues of fluoride after the direct, postharvest fumigation with sulfuryl fluoride of different produce and grains. These tolerances highlight the safety of this product (40 CFR 180.575).

Extensive studies have verified that fumigation with sulfuryl fluoride does not affect the quality of foods, which support the use of this fumigant in the food processing industry. After application, the sulfuryl fluoride molecules splits into two residues, the fluoride anion (F^-) and sulfate (SO_4^{2-}). The latter residue is found naturally in living systems and does not pose any toxicity. In addition, the sulfuryl fluoride residues are transient in food commodities and rapidly decrease to amounts that have no technical effect on the product and do not pose any public health hazards; usually around few parts per billions (Meikle and Stewart, 1962; Scheffrahn et al., 1989).

Sulfuryl fluoride does not have any reactivity with inert materials. Specifically, this inorganic gas will not react with any packaging component or remain present in its complete formula on food contact surfaces. Thus, after the application of sulfuryl fluoride in the DC, there were no residues left in packaging material or any product because the fumigant did not directly contact products.

It is our conclusion that the fumigation performed is consistent with the following:

- The fumigant used is a registered, inert gas that is appropriate when there is a need to control rodent pest infestations in food warehousing/manufacturing facilities.
- Consistent with the above risk-based matrix, the impervious packaging materials (*e.g.*, plastics, resins, poly-foil films, metal, mylar bag materials, paper-poly film, etc.) are not affected by exposure to the fumigant gas.
- The fumigant was applied under ambient (normal room pressure) as an area flood gas and did not come into direct product contact for any product packaged in a container that is sealed via: vacuum, induction, shrink-wrap overwrap, heat-melt, or hermetically sealed

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before high thermal processing. Therefore, the fumigant represents no risk to products of any kind packaged in that manner consistent with the above risk-based matrix.

- For products packaged in containers that are not "hermetically sealed" (such as cardboard boxes, paper wrapper, etc.), the gas fumigant will penetrate the interior of such packaging. However, the gaseous fumigant will "degas" over a short period of time as it seeks to reach equilibrium with the ambient air, causing it to dissipate to 0.5 ppm or less upon opening of the package to the ambient environment.
- The gas fumigant used does not interact with foods, OTC drugs or medical devices and does not stay on incidentally exposed/open product, or on/within packaging materials or packaged product.
- The application was performed by a licensed company with decades of experience in performing fumigation practices in a variety of food commodities.

Based on the foregoing, the fumigation process was successful. Fumigation was meant to rapidly reduce the population of rodents to further control and eliminate them from the DC and it did just that. In addition, the use of the fumigant gas does not pose any product safety or public health concerns.

In summary, our assessment shows the following:

- There is no health risk associated with the fumigation process used at the DC.
- The current reconditioning practices are identifying and segregating potentially contaminated product. Some product is disposed, and product that is reconditioned has barriers that would prevent the incorporation of any outside hazard into the product.
- Based on the premise of the package material/configuration matrix and the inspection and reconditioning process, there is no risk of direct rodent filth contamination to product that has been reconditioned.
- There is no potential for product contamination from the fumigation process.

Based on these assessments, the product in the DC did not change their adulterated/potentially adulterated status because of the fumigation and all product is being inspected to identify, segregate and recondition, if appropriate, any potentially adulterated product. In addition, EAS concurs with the results of this assessment and the conclusions set forth herein.

Sincerely,

Brad Hammock

Brad Hammock
Director Environmental, Safety and Health

500 Volvo Parkway, Chesapeake, VA 23320
Main (757) 321-5000 Fax (757) 321-5949

Brad Hammock
Email: bthammoc@dollartree.com

References

- Title 40 of the Code of Federal Regulation, Part 180, Subpart 145, Fluorine compounds; tolerances for residues. Available at: https://www.ecfr.gov/current/title-40/chapter-I/subchapter-E/part-180/subpart-C/section-180.145.
- Scheffrahn, R. H., R. C. Hsu, and N. Y. Su. 1989. Fluoride and sulfate residues in foods fumigated with sulfuryl fluoride. J. Agric. Food Chem. 37: 203-206.
- Meikle, R. W. and D. J. Stewart. 1962. Structural fumigants, the residue potential of sulfuryl fluoride, methyl bromide, and methanesulfonyl fluoride in structural fumigations. J. Ag. Food Chem. 10: 393-379.

Attachments

- U01-129-032 Profume_Tech_Bulletin_US_r6 012018 (6)
- U01-129-171 US ProFume Product Bulletin 01122018
- 2022-1-14 Family Dollar Fumiguide report
- Applicator Manual for ProFume gas fumigant

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Main (757) 321-5000 Fax (757) 321-5949

